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C. R. Bard, Inc. and
Bard Peripheral Vascular, Inc.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability MDL NO. 15-02641-PHX-DGC
Litigation

This Document Relates to:

ALANA BOND and
ROBERT BOND,

Plaintiffs,

CASE NO. CV-16-00598-PHX-DGC

v.

C. R. BARD, INC., a New Jersey
Corporation; and BARD PERIPHERAL
VASCULAR INC., (a subsidiary and/or
division of defendant C. R. BARD, INC.)
an Arizona Corporation,

**DEFENDANTS C. R. BARD, INC. AND
BARD PERIPHERAL VASCULAR,
INC.'S ANSWER AND DEFENSES TO
PLAINTIFFS' COMPLAINT AND
DEMAND FOR TRIAL BY JURY**

Defendants.

Defendants C. R. Bard, Inc. (“Bard”) and Bard Peripheral Vascular, Inc. (“BPV”) (collectively “Defendants”), through undersigned counsel, hereby answer the complaint of Plaintiffs Alana and Robert Bond (the “Plaintiffs’ Complaint”) as follows:

1. Defendants admit that Plaintiffs have brought this civil action for damages but deny that Plaintiffs have suffered any personal injuries caused by Defendants, deny that Defendants are liable to Plaintiffs, and deny that Plaintiffs are entitled to any damages from Defendants.

PARTIES, JURISDICTION, AND VENUE

2. Defendants are without knowledge or information sufficient to admit or deny the allegations contained in Paragraph 2 of Plaintiffs’ Complaint and, on that basis, deny them.

3. Defendants deny that Bard is a Delaware Corporation. Defendants admit that Bard is a New Jersey Corporation and that Bard is authorized to do business, and does business, in the States of Tennessee and New Jersey. Defendants admit that Bard owns a facility where vena cava filters are manufactured, including filters under the trademark Denali™ Filter System. Bard denies any remaining allegations contained in Paragraph 3 of Plaintiffs’ Complaint including any allegations contained in Footnote 1 of the Plaintiffs’ Complaint.

4. Defendants admit that BPV is an Arizona Corporation and that BPV is authorized to do business, and does business, in the State of New Jersey. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV has designed, sold, marketed, and distributed filters under the trademark Denali™ Filter System. Defendants further admit that BPV is a wholly owned subsidiary of Bard. Defendants deny any remaining allegations contained in Paragraph 4 of the Complaint.

JURISDICTION AND VENUE

5. Defendants do not contest that the injuries and damages alleged within Plaintiffs’ Complaint exceed the jurisdictional limit of this Court. However, Defendants deny

1 that they are liable to Plaintiffs for any amount whatsoever and deny that Plaintiffs have
 2 suffered any damages whatsoever. Defendants do not dispute that, based on the facts as
 3 alleged by Plaintiffs, which have not been and could not have been confirmed by Defendants,
 4 this Court appears to have jurisdiction over this dispute.

5 6. Defendants admit that the Judicial Panel of Multidistrict Litigation recently
 6 consolidated certain claims related to Bard IVC filters into MDL No. 2461, the venue for
 7 which is the United States District Court for the District of Arizona and over which Judge
 8 David Campbell presides.

9 **GENERAL BACKGROUND ALLEGATIONS**

10 7. Defendants are without knowledge or information sufficient to form a belief as
 11 to the truth of the allegations regarding the trade name of any inferior vena cava filter
 12 implanted in Plaintiff and, on that basis, deny them. Defendants are without knowledge or
 13 information sufficient to form a belief as to the truth of the remaining allegations contained in
 14 Paragraph 7 of Plaintiffs' Complaint.

15 8. Defendants admit that Bard owns a facility where vena cava filters are
 16 manufactured. Defendants further admit that BPV designs, sells, markets, and distributes
 17 inferior vena cava filters and that BPV has designed, sold, marketed, and distributed filters
 18 under the trademark Denali™ Filter Systems. Defendants further admit that inferior vena
 19 cava filters are intended to prevent injury or death resulting from venous thrombosis and
 20 pulmonary embolism. Defendants deny any remaining allegations contained in Paragraph 8 of
 21 Plaintiffs' Complaint.

22 9. Defendants deny the allegations contained in Paragraph 9 of Plaintiffs'
 23 Complaint, including all sub-parts thereof.

24 **IVC FILTERS GENERALLY**

25 10. Defendants lack knowledge or information sufficient to admit or deny the
 26 allegation regarding the trademark on any product at issue in this case. Defendants admit that
 27 Bard owns a facility where vena cava filters are manufactured (including filters under the
 28

1 trademark Denali™ Filter System) and further admit that BPV designs, sells, markets, and
2 distributes inferior vena cava filters (including filters under the trademark Denali™ Filter
3 System). Defendants further admit that the Denali™ Filter System has been marketed, sold,
4 and distributed since 2013. Defendants deny any remaining allegations contained in
5 Paragraph 10 of Plaintiffs' Complaint.

6 11. Defendants lack knowledge or information sufficient to admit or deny the
7 allegation regarding the time frame when inferior vena cava filters were first introduced on
8 the market or the identity of manufacturers of inferior vena cava filters. Defendants deny any
9 remaining allegations of Paragraph 11 of Plaintiffs' Complaint.

10 12. Defendants admit that inferior vena cava filters are intended to prevent injury or
11 death resulting from venous thrombosis and pulmonary embolism. Defendants further admit
12 that inferior vena cava filters may be designed for permanent placement, temporary
13 placement, or both. Defendants deny any remaining allegations of Paragraph 12 of Plaintiffs'
14 Complaint.

15 13. Defendants admit that the inferior vena cava is a large vein that receives blood
16 from the lower regions of the body and delivers it to the right atrium of the heart. Defendants
17 further admit that deep vein thrombosis and pulmonary emboli present dangerous risks to
18 human health, including sometimes death. Defendants deny any remaining allegations of
19 Paragraph 13 of Plaintiffs' Complaint.

20 14. Defendants admit that certain people are at an increased risk for the
21 development of deep vein thrombosis and pulmonary embolus, but lack sufficient information
22 to admit or deny the allegations regarding the various risk factors which may predispose an
23 individual to deep vein thrombosis or pulmonary emboli and thus deny them. Defendants
24 deny any remaining allegations of Paragraph 14 of Plaintiffs' Complaint.

25 15. Defendants admit that patients at a high risk for developing deep vein
26 thrombosis and pulmonary embolism are frequently treated with anticoagulation therapy,
27 including but not limited to the medications listed in Paragraph 15 of Plaintiffs' Complaint.
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1 Defendants further admit that inferior vena cava filters may also be used to treat patients who
2 are at a high risk for developing deep vein thrombosis and pulmonary embolism. Defendants
3 lack knowledge or information sufficient to admit or deny any remaining allegations
4 contained in Paragraph 15 of Plaintiffs' Complaint and, on that basis, deny them.

5 16. Defendants lack knowledge or information sufficient to admit or deny the
6 allegation regarding the time frame when inferior vena cava filters were first introduced on
7 the market. Defendants deny any remaining allegations of Paragraph 16 of Plaintiffs'
8 Complaint.

9 17. Defendants lack knowledge or information sufficient to admit or deny the
10 allegations regarding the medical community's concerns regarding the desirability of a
11 retrievable filter or the intent of manufacturers in general regarding the development of
12 retrievable filters. Defendants deny any remaining allegations of Paragraph 17 of Plaintiffs'
13 Complaint.

14 18. Defendants admit that a nickel-titanium alloy named Nitinol is used in the
15 manufacture of the Denali™ Filter. Defendants admit that Nitinol contains shape memory.
16 Defendants lack knowledge or information sufficient to admit or deny the allegations as to the
17 development or other uses of Nitinol. Defendants deny any remaining allegations of
18 Paragraph 18 of Plaintiffs' Complaint.

19 19. Defendants admit that Bard previously designed, manufactured, and sold a
20 device named the Recovery® Filter System. Defendants deny the remaining allegations of
21 Paragraph 19 of Plaintiffs' Complaint.

22 20. Defendants deny the Recovery® Filter System was unreasonably dangerous or
23 defective in any manner. Defendants admit that there are various well-documented
24 complications that may occur as a result of the fracture and/or migration of any inferior vena
25 cava filter. Defendants further admit that it is well-documented that many instances of filter
26 fracture and/or migration result in no complications whatsoever, but, rather, are completely
27 asymptomatic. By way of further response, Defendants state that there are incidents related
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1 to the occurrence of known complications associated with every manufacturer of inferior
2 vena cava filters. Defendants deny the remaining allegations of Paragraph 20 of Plaintiffs'
3 Complaint.

4 21. Defendants deny the Recovery® Filter System was unreasonably dangerous or
5 defective in any manner. Defendants state that there are incidents related to the occurrence of
6 known complications associated with every manufacturer of inferior vena cava filters.
7 Defendants deny any remaining allegations contained in Paragraph 21 of the Plaintiffs'
8 Complaint.

9 22. Defendants deny the Recovery® Filter System was unreasonably dangerous or
10 defective in any manner. Defendants deny the remaining allegations contained in Paragraph
11 22 of the Plaintiffs' Complaint, including any allegations contained in Footnote 2 of the
12 Plaintiffs' Complaint.

13 23. Defendants admit that, as part of their continuing efforts to constantly evaluate
14 the medical devices they sell, in conjunction with the ever-changing state-of-the-art, they are
15 continually striving to improve the life-saving performance of those devices. The Denali™
16 Filter was developed in furtherance of those efforts. Defendants deny the remaining
17 allegations contained in Paragraph 23 of Plaintiffs' Complaint.

18 24. Defendants admit the Denali™ Filter System was cleared by the United States
19 Food and Drug Administration pursuant to an application submitted under Section 510(k) of
20 the Food, Drug and Cosmetic Act in 2013. The allegations pertaining to the requirements of
21 Section 510(k) are conclusions of law to which no answer is required. Defendants deny any
22 remaining allegations contained in Paragraph 24 of Plaintiffs' Complaint.

23 25. Defendants admit the Denali™ Filter System was cleared by the United States
24 Food and Drug Administration pursuant to an application submitted under Section 510(k) of
25 the Food, Drug and Cosmetic Act in 2013. Defendants deny any remaining allegations
26 contained in Paragraph 25 of Plaintiffs' Complaint.

1 26. Defendants admit that both the Recovery® Filter and the Denali™ Filter have a
2 similar design, consisting of twelve, shape-memory Nitinol wires emanating from a central
3 Nitinol sleeve. Defendants further admit that, in both devices, the twelve wires form two
4 levels of filtration for emboli: the legs provide the lower level of filtration, and the arms
5 provide the upper level of filtration. Defendants deny any remaining allegations of Paragraph
6 26 of Plaintiffs' Complaint.

7 27. Defendants admit that both the Recovery® Filter and the Denali™ Filter are
8 made of Nitinol and that the Denali™ Filter is electropolished. Defendants deny any
9 remaining allegations of Paragraph 27 of Plaintiffs' Complaint.

10 28. Defendants admit that the Denali™ Filter was designed to be inserted
11 endovascularly. Defendants further admit that the Denali™ Filter is designed to be delivered
12 via an introducer sheath, which is included in the delivery system for the device. Defendants
13 deny any remaining allegations of Paragraph 28 of Plaintiffs' Complaint.

14 29. Defendants lack knowledge or information sufficient to admit or deny the
15 allegations contained in Paragraph 29 of the Plaintiffs' Complaint regarding the "typical"
16 practices of physicians, and on that basis, such allegations are denied. Defendants deny any
17 remaining allegations of Paragraph 29 of the Plaintiffs' Complaint.

18 30. Defendants deny the allegations contained in Paragraph 30 of the Plaintiffs'
19 Complaint.

20 31. Defendants deny the allegations contained in Paragraph 31 of the Plaintiffs'
21 Complaint.

22 32. Defendants admit that, as part of their continuing efforts to constantly evaluate
23 the medical devices they sell, in conjunction with the ever-changing state-of-the-art, they are
24 continually striving to improve the life-saving performance of those devices. The Denali™
25 Filter was developed in furtherance of those efforts. Defendants deny any remaining
26 allegations of Paragraph 32 of the Plaintiffs' Complaint, including any allegations contained
27 in Footnote 3 of the Plaintiffs' Complaint.
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1 33. Defendant Bard admits that it periodically receives notice of incidents involving
2 a device it manufactured and, when appropriate, Bard reports such incidents to the United
3 States Food and Drug Administration (“FDA”). By way of further response, Bard states that
4 there are incidents related to the occurrence of known complications associated with every
5 manufacturer of vena cava filters. Defendants deny the remaining allegations of Paragraph
6 33 of the Plaintiffs’ Complaint.

7 34. Defendants admit that there are various well-documented complications that
8 may occur as the result of the fracture and/or migration of any inferior vena cava filter. Bard
9 states that there are incidents related to the occurrence of known complications associated
10 with every manufacturer of inferior vena cava filters. By way of further response, Bard states
11 that information available in the public domain, including the FDA MAUDE database, is not
12 a comprehensive analysis of all instances of such complications. Defendants deny the
13 remaining allegations of Paragraph 34 of Plaintiffs’ Complaint, including any allegations
14 contained in Footnote 4.

15 35. Defendants admit that there are various well-documented complications that
16 may occur as the result of the fracture and/or migration of any inferior vena cava filter.
17 Defendants state that there are incidents related to the occurrence of known complications
18 associated with every manufacturer of inferior vena cava filters. By way of further response,
19 Defendants state that information available in the public domain, including the FDA MAUDE
20 database, is not a comprehensive analysis of all instances of such complications. Defendants
21 deny the remaining allegations of Paragraph 35 of Plaintiffs’ Complaint.

22 36. Defendants admit that there are various well-documented complications that
23 may occur as a result of the fracture and/or migration of any inferior vena cava filter.
24 Defendants further admit that it is well documented than many instances of filter fracture
25 and/or migration result in no complications whatsoever but, rather, are completely
26 asymptomatic. By way of further response, Bard states that there are incidents related to the
27 occurrence of known complications associated with every manufacturer of inferior vena cava
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1 filters. Defendants deny the remaining allegations of Paragraph 36 of the Plaintiffs'
2 Complaint, including all sub-parts thereof.

3 37. Defendants deny the allegations of Paragraph 37 of the Plaintiffs' Complaint.

4 38. Defendants deny the allegations of Paragraph 38 of the Plaintiffs' Complaint.

5 39. Defendants admit that, in the course of his very limited study, Dr. Hull makes
6 certain recommendations regarding patient and physician follow-up of Recovery® Filters.
7 Defendants deny the Denali™ Filter is unreasonably dangerous or defective in any manner.
8 Defendants deny the remaining allegations of Paragraph 39 of the Plaintiffs' Complaint,
9 including the allegations contained in Footnote 5.

10 40. Defendants admit that cardiac catheterization is one means of identifying struts
11 that have fractured. Defendants deny the remaining allegations of Paragraph 40 of the
12 Plaintiffs' Complaint.

13 41. Defendants admit that CT scanning, cardiac catheterization, filter removal,
14 and/or surgical intervention are some of the ways in which a physician may treat struts that
15 have fractured. Defendants deny the remaining allegations of Paragraph 41 of the Plaintiffs'
16 Complaint, including all sub-parts thereof.

17 42. Defendants are without knowledge or information sufficient to form a belief as
18 to the truth of the allegations regarding the trade name of any inferior vena cava filter
19 implanted in Plaintiff and, on that basis, denies them. Defendants deny the remaining
20 allegations contained in Paragraph 42 of Plaintiffs' Complaint.

21 43. Defendants deny the allegations contained in Paragraph 43 of the Plaintiffs'
22 Complaint.

23 44. Defendants deny the allegations contained in Paragraph 44 of the Plaintiffs'
24 Complaint.

25 45. Defendants deny the allegations contained in Paragraph 45 of the Plaintiffs'
26 Complaint, including all sub-parts thereof.

1 46. Defendants deny the allegations contained in Paragraph 46 of the Plaintiffs'
2 Complaint.

3 47. Bard admits that on August 9, 2010, the Food and Drug Administration posted
4 an initial communication titled "Inferior Vena Cava (IVC) Filters: Initial Communication:
5 Risk of Adverse Events with Long Term Use," and that Initial Communication stated that
6 "Since 2005, the FDA has received 921 device adverse event reports involving IVC filters."
7 However, to the extent Paragraph 47 purports to cast liability either directly or indirectly
8 upon Defendants, said Paragraph is expressly denied.

9 48. Defendants deny the allegations contained in Paragraph 48 of the Plaintiffs'
10 Complaint.

11 49. Defendants deny the allegations contained in Paragraph 49 of the Plaintiffs'
12 Complaint, including all sub-parts thereof.

13 50. Defendants deny the allegations contained in Paragraph 50 of the Plaintiffs'
14 Complaint.

15 51. Defendants deny the allegations contained in Paragraph 51 of the Plaintiffs'
16 Complaint.

17 52. In response to the allegations contained in Paragraph 52, Bard admits only that
18 the regulation cited in Paragraph 52 exists. To the extent the allegations in Paragraph 52 of
19 Plaintiffs' Complaint purport to cast liability upon Defendants, either directly or indirectly,
20 those allegations are denied.

21 53. In response to the allegations contained in Paragraph 53, Bard admits only that
22 the regulation cited in Paragraph 53 exists. To the extent the allegations in Paragraph 53 of
23 Plaintiffs' Complaint purport to cast liability upon Defendants, either directly or indirectly,
24 those allegations are denied.

25 54. In response to the allegations contained in Paragraph 54, Bard admits only that
26 the regulation cited in Paragraph 54 exists. To the extent the allegations in Paragraph 54 of
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1 Plaintiffs' Complaint purport to cast liability upon Defendants, either directly or indirectly,
2 those allegations are denied.

3 55. The allegations contained in Paragraph 55 of Plaintiffs' Complaint are
4 conclusions of law, which require no response. To the extent a response is required,
5 Defendants deny those allegations.

6 56. In response to the allegations contained in Paragraph 56, Bard admits only that
7 the statute cited in Paragraph 56 exists. To the extent the allegations in Paragraph 56 of
8 Plaintiffs' Complaint purport to cast liability upon Defendants, either directly or indirectly,
9 those allegations are denied.

10 57. In response to the allegations contained in Paragraph 57, Bard admits only that
11 the statute cited in Paragraph 57 exists. To the extent the allegations in Paragraph 57 of
12 Plaintiffs' Complaint purport to cast liability upon Defendants, either directly or indirectly,
13 those allegations are denied.

14 58. In response to the allegations contained in Paragraph 58, Bard admits only that
15 the statute cited in Paragraph 58 exists. To the extent the allegations in Paragraph 58 of
16 Plaintiffs' Complaint purport to cast liability upon Defendants, either directly or indirectly,
17 those allegations are denied.

18 59. In response to the allegations contained in Paragraph 59, Bard admits only that
19 the regulation cited in Paragraph 59 exists. To the extent the allegations in Paragraph 59 of
20 Plaintiffs' Complaint purport to cast liability upon Defendants, either directly or indirectly,
21 those allegations are denied.

22 60. In response to the allegations contained in Paragraph 60, Bard admits only that
23 the regulation cited in Paragraph 60 exists. To the extent the allegations in Paragraph 60 of
24 Plaintiffs' Complaint purport to cast liability upon Defendants, either directly or indirectly,
25 those allegations are denied.

26 61. In response to the allegations contained in Paragraph 61, Bard admits only that
27 the regulation cited in Paragraph 61 exists. To the extent the allegations in Paragraph 61 of
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1 Plaintiffs' Complaint purport to cast liability upon Defendants, either directly or indirectly,
2 those allegations are denied.

3 62. In response to the allegations contained in Paragraph 62, Bard admits only that
4 the regulation cited in Paragraph 62 exists. To the extent the allegations in Paragraph 62 of
5 Plaintiffs' Complaint purport to cast liability upon Defendants, either directly or indirectly,
6 those allegations are denied.

7 63. In response to the allegations contained in Paragraph 63, Bard admits only that
8 the regulation cited in Paragraph 63 exists. To the extent the allegations in Paragraph 63 of
9 Plaintiffs' Complaint purport to cast liability upon Defendants, either directly or indirectly,
10 those allegations are denied.

11 64. In response to the allegations contained in Paragraph 64, Bard admits only that
12 the regulation cited in Paragraph 64 exists. To the extent the allegations in Paragraph 64 of
13 Plaintiffs' Complaint purport to cast liability upon Defendants, either directly or indirectly,
14 those allegations are denied.

15 65. In response to the allegations contained in Paragraph 65, Bard admits only that
16 the regulation cited in Paragraph 65 exists. To the extent the allegations in Paragraph 65 of
17 Plaintiffs' Complaint purport to cast liability upon Defendants, either directly or indirectly,
18 those allegations are denied.

19 66. In response to the allegations contained in Paragraph 66, Bard admits only that
20 the regulation cited in Paragraph 66 exists. To the extent the allegations in Paragraph 66 of
21 Plaintiffs' Complaint purport to cast liability upon Defendants, either directly or indirectly,
22 those allegations are denied.

23 67. In response to the allegations contained in Paragraph 67, Bard admits only that
24 the regulation cited in Paragraph 67 exists. To the extent the allegations in Paragraph 67 of
25 Plaintiffs' Complaint purport to cast liability upon Defendants, either directly or indirectly,
26 those allegations are denied.

1 68. In response to the allegations contained in Paragraph 68, Bard admits only that
2 the regulation cited in Paragraph 68 exists. To the extent the allegations in Paragraph 68 of
3 Plaintiffs' Complaint purport to cast liability upon Defendants, either directly or indirectly,
4 those allegations are denied.

5 69. In response to the allegations contained in Paragraph 69, Bard admits only that
6 the regulation cited in Paragraph 69 exists. To the extent the allegations in Paragraph 69 of
7 Plaintiffs' Complaint purport to cast liability upon Defendants, either directly or indirectly,
8 those allegations are denied.

9 70. In response to the allegations contained in Paragraph 70, Bard admits only that
10 the regulation cited in Paragraph 70 exists. To the extent the allegations in Paragraph 70 of
11 Plaintiffs' Complaint purport to cast liability upon Defendants, either directly or indirectly,
12 those allegations are denied.

13 71. In response to the allegations contained in Paragraph 71, Bard admits only that
14 the regulation cited in Paragraph 71 exists. To the extent the allegations in Paragraph 71 of
15 the Plaintiffs' Complaint purport to cast liability upon Defendants, either directly or
16 indirectly, those allegations are denied.

17 72. In response to the allegations contained in Paragraph 72, Bard admits only that
18 the regulation cited in Paragraph 72 exists. To the extent the allegations in Paragraph 72 of
19 Plaintiffs' Complaint purport to cast liability upon Defendants, either directly or indirectly,
20 those allegations are denied.

21 73. In response to the allegations contained in Paragraph 73, Bard admits only that
22 the regulation cited in Paragraph 73 exists. To the extent the allegations in Paragraph 73 of
23 Plaintiffs' Complaint purport to cast liability upon Defendants, either directly or indirectly,
24 those allegations are denied.

25 74. In response to the allegations contained in Paragraph 74, Bard admits only that
26 the regulation cited in Paragraph 74 exists. To the extent the allegations in Paragraph 74 of
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1 Plaintiffs' Complaint purport to cast liability upon Defendants, either directly or indirectly,
2 those allegations are denied.

3 75. In response to the allegations contained in Paragraph 75, Bard admits only that
4 the regulation cited in Paragraph 75 exists. To the extent the allegations in Paragraph 75 of
5 Plaintiffs' Complaint purport to cast liability upon Defendants, either directly or indirectly,
6 those allegations are denied.

7 76. In response to the allegations contained in Paragraph 76, Bard admits only that
8 the regulation cited in Paragraph 76 exists. To the extent the allegations in Paragraph 76 of
9 Plaintiffs' Complaint purport to cast liability upon Defendants, either directly or indirectly,
10 those allegations are denied, including all sub-parts thereof.

11 77. In response to the allegations contained in Paragraph 77, Bard admits only that
12 the regulation cited in Paragraph 77 exists. To the extent the allegations in Paragraph 77 of
13 Plaintiffs' Complaint purport to cast liability upon Defendants, either directly or indirectly,
14 those allegations are denied.

15 78. In response to the allegations contained in Paragraph 78, Bard admits only that
16 the regulation cited in Paragraph 78 exists. To the extent the allegations in Paragraph 78 of
17 Plaintiffs' Complaint purport to cast liability upon Defendants, either directly or indirectly,
18 those allegations are denied.

19 79. In response to the allegations contained in Paragraph 79, Bard admits only that
20 the regulation cited in Paragraph 79 exists. To the extent the allegations in Paragraph 79 of
21 Plaintiffs' Complaint purport to cast liability upon Defendants, either directly or indirectly,
22 those allegations are denied.

23 80. In response to the allegations contained in Paragraph 80, Bard admits only that
24 the regulation cited in Paragraph 80 exists. To the extent the allegations in Paragraph 80 of
25 Plaintiffs' Complaint purport to cast liability upon Defendants, either directly or indirectly,
26 those allegations are denied.

1 81. In response to the allegations contained in Paragraph 81, Bard admits only that
2 the regulation cited in Paragraph 81 exists. To the extent the allegations in Paragraph 81 of
3 Plaintiffs' Complaint purport to cast liability upon Defendants, either directly or indirectly,
4 those allegations are denied.

5 82. In response to the allegations contained in Paragraph 82, Bard admits only that
6 the regulation cited in Paragraph 82 exists. To the extent the allegations in Paragraph 82 of
7 Plaintiffs' Complaint purport to cast liability upon Defendants, either directly or indirectly,
8 those allegations are denied.

9 83. In response to the allegations contained in Paragraph 83, Bard admits only that
10 the regulation cited in Paragraph 83 exists. To the extent the allegations in Paragraph 83 of
11 Plaintiffs' Complaint purport to cast liability upon Defendants, either directly or indirectly,
12 those allegations are denied.

13 84. In response to the allegations contained in Paragraph 84, Bard admits only that
14 the regulation cited in Paragraph 84 exists. To the extent the allegations in Paragraph 84 of
15 Plaintiffs' Complaint purport to cast liability upon Defendants, either directly or indirectly,
16 those allegations are denied.

17 85. In response to the allegations contained in Paragraph 85, Bard admits only that
18 the regulation cited in Paragraph 85 exists. To the extent the allegations in Paragraph 85 of
19 Plaintiffs' Complaint purport to cast liability upon Defendants, either directly or indirectly,
20 those allegations are denied.

21 86. In response to the allegations contained in Paragraph 86, Bard admits only that
22 the regulation cited in Paragraph 86 exists. To the extent the allegations in Paragraph 86 of
23 Plaintiffs' Complaint purport to cast liability upon Defendants, either directly or indirectly,
24 those allegations are denied.

25 87. In response to the allegations contained in Paragraph 87, Bard admits only that
26 the regulation cited in Paragraph 87 exists. To the extent the allegations in Paragraph 87 of
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1 Plaintiffs' Complaint purport to cast liability upon Defendants, either directly or indirectly,
2 those allegations are denied, including all sub-parts thereof.

3 88. Defendants admit the Denali™ Filter System was cleared by the United States
4 Food and Drug Administration pursuant to an application submitted under Section 510(k) of
5 the Food, Drug and Cosmetic Act in 2013. Defendants deny any remaining allegations
6 contained in Paragraph 88 of Plaintiffs' Complaint.

7 89. Defendants admit the Denali™ Filter System was cleared by the United States
8 Food and Drug Administration pursuant to an application submitted under Section 510(k) of
9 the Food, Drug and Cosmetic Act in 2013. Defendants deny any remaining allegations
10 contained in Paragraph 89 of Plaintiffs' Complaint.

11 90. Defendants deny the allegations contained in Paragraph 90 of Plaintiffs'
12 Complaint.

13 91. Defendants deny the allegations contained in Paragraph 91 of Plaintiffs'
14 Complaint.

15 92. Defendants deny the allegations contained in Paragraph 92 of Plaintiffs'
16 Complaint.

17 93. Defendants deny the allegations contained in Paragraph 93 of Plaintiffs'
18 Complaint.

19 94. Defendants deny the allegations contained in Paragraph 94 of Plaintiffs'
20 Complaint.

21 95. Defendants deny the allegations contained in Paragraph 95 of Plaintiffs'
22 Complaint.

23 **FRUADULENT [sic] CONCEALMENT**

24 96. Defendants deny the allegations contained in Paragraph 96 of Plaintiffs'
25 Complaint.

26 97. Defendants deny the allegations contained in Paragraph 97 of Plaintiffs'
27 Complaint.

1 98. Defendants deny the allegations contained in Paragraph 98 of Plaintiffs'
2 Complaint.

3 **CORPORATE/VICARIOUS LIABILITY**

4 99. Defendants deny the allegations contained in Paragraph 99 of Plaintiffs'
5 Complaint.

6 100. Defendants deny the allegations contained in Paragraph 100 of Plaintiffs'
7 Complaint.

8 101. Defendants deny the allegations contained in Paragraph 101 of Plaintiffs'
9 Complaint.

10 102. Defendants deny the allegations contained in Paragraph 102 of Plaintiffs'
11 Complaint.

12 **FIRST CAUSE OF ACTION**

13 **NEGLIGENCE**

14 103. Defendants incorporate by reference their responses to Paragraphs 1-102 of
15 Plaintiffs' Complaint as if fully set forth herein.

16 104. Defendants deny the allegations of Paragraph 104 of Plaintiffs' Complaint as
17 stated. By way of further response, Defendants admit that Bard owns a facility where vena
18 cava filters are manufactured and that filters under the trademark Denali™ Filter System were
19 manufactured at that facility. Defendants further admit that BPV designs, sells, markets, and
20 distributes inferior vena cava filters and that BPV designed, sold, marketed, and distributed
21 filters under the trademark Denali™ Filter System. Defendants deny any remaining
22 allegations contained in Paragraph 104 of Plaintiffs' Complaint.

23 105. Defendants are without information or knowledge sufficient to form a belief as
24 to the truth of the allegations regarding the trade name of any inferior vena cava filter
25 implanted in Plaintiff and, on that basis, deny them. Defendants admit that Bard owns a
26 facility where vena cava filters are manufactured and that filters under the trademark
27 Denali™ Filter System were manufactured at that facility. Defendants further admit that BPV
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1 designs, sells, markets, and distributes inferior vena cava filters and that BPV designed, sold,
 2 marketed, and distributed filters under the trademark Denali™ Filter System. Defendants
 3 deny any remaining allegations contained in Paragraph 105 of Plaintiffs' Complaint.

4 106. The allegations contained in Paragraph 106 regarding Defendants' duty are
 5 conclusions of law, and no answer is required. To the extent a response is required,
 6 Defendants deny the allegations. Defendants deny the remaining allegations contained in
 7 Paragraph 106 of Plaintiffs' Complaint.

8 107. Defendants deny the allegations contained in Paragraph 107 of Plaintiffs'
 9 Complaint.

10 108. Defendants deny the allegations contained in Paragraph 108 of Plaintiffs'
 11 Complaint, including all sub-parts thereof.

12 109. Defendants deny the allegations contained in Paragraph 109 of Plaintiffs'
 13 Complaint.

14 110. Defendants deny the allegations contained in Paragraph 110 of Plaintiffs'
 15 Complaint.

16 111. Defendants deny the allegations contained in Paragraph 111 of Plaintiffs'
 17 Complaint, including all sub-parts thereof.

18 112. Defendants deny the allegations contained in Paragraph 112 of Plaintiffs'
 19 Complaint.

20 113. Defendants deny the allegations contained in Paragraph 113 of Plaintiffs'
 21 Complaint.

22 **SECOND CAUSE OF ACTION**

23 **STRICT PRODUCT LIABILITY – FAILURE TO WARN**

24 114. Defendants incorporate by reference their responses to Paragraphs 1-113 of
 25 Plaintiffs' Complaint as if fully set forth herein.

26 115. Defendants are without knowledge or information sufficient to form a belief as
 27 to the truth of the allegations regarding the trade name of any inferior vena cava filter
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1 implanted in Plaintiff and, on that basis, deny them. By way of further response, Defendants
2 admit that Bard owns a facility where vena cava filters are manufactured and that filters under
3 the trademark Denali™ Filter System were manufactured at that facility. Defendants further
4 admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV
5 designed, sold, marketed, and distributed filters under the trademark Denali™ Filter System.
6 Defendants deny any remaining allegations contained in Paragraph 115 of Plaintiffs'
7 Complaint.

8 116. Defendants deny the allegations contained in Paragraph 116 of Plaintiffs'
9 Complaint.

10 117. The allegations contained in Paragraph 117 regarding Defendants' duty are
11 conclusions of law, and no answer is required. To the extent a response is required,
12 Defendants deny the allegations. Defendants deny the remaining allegations contained in
13 Paragraph 117 of Plaintiffs' Complaint.

14 118. Defendants deny the allegations contained in Paragraph 118 of Plaintiffs'
15 Complaint.

16 119. Defendants deny the allegations contained in Paragraph 119 of Plaintiffs'
17 Complaint.

18 120. Defendants deny the allegations contained in Paragraph 120 of Plaintiffs'
19 Complaint.

20 121. Defendants deny the allegations contained in Paragraph 121 of Plaintiffs'
21 Complaint.

22 122. Defendants deny the allegations contained in Paragraph 122 of Plaintiffs'
23 Complaint.

24 123. Defendants deny the allegations contained in Paragraph 123 of Plaintiffs'
25 Complaint.

26 124. Defendants deny the allegations contained in Paragraph 124 of Plaintiffs'
27 Complaint.

THIRD CAUSE OF ACTION

STRICT PRODUCTS LIABILITY – DESIGN DEFECTS

125. Defendants incorporate by reference their responses to Paragraphs 1-124 of Plaintiffs' Complaint as if fully set forth herein.

126. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding the trade name of any inferior vena cava filter implanted in Plaintiff and, on that basis, deny them. By way of further response, Defendants admit that Bard owns a facility where vena cava filters are manufactured and that filters under the trademark Denali™ Filter System were manufactured at that facility. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV designed, sold, marketed, and distributed filters under the trademark Denali™ Filter System. Defendants deny any remaining allegations contained in Paragraph 126 of Plaintiffs' Complaint.

127. Defendants deny the allegations contained in Paragraph 127 of Plaintiffs' Complaint.

128. Defendants deny the allegations contained in Paragraph 128 of Plaintiffs' Complaint.

129. Defendants deny the allegations contained in Paragraph 129 of Plaintiffs' Complaint.

130. Defendants deny the allegations contained in Paragraph 130 of Plaintiffs' Complaint.

131. Defendants deny the allegations contained in Paragraph 131 of Plaintiffs' Complaint.

132. Defendants deny the allegations contained in Paragraph 132 of Plaintiffs' Complaint.

FOURTH CAUSE OF ACTION

STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT

133. Defendants incorporate by reference their responses to Paragraphs 1-132 of Plaintiffs' Complaint as if fully set forth herein.

134. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding the trade name of any inferior vena cava filter implanted in Plaintiff and, on that basis, deny them. By way of further response, Defendants admit that Bard owns a facility where vena cava filters are manufactured and that filters under the trademark Denali™ Filter System were manufactured at that facility. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV designed, sold, marketed, and distributed filters under the trademark Denali™ Filter System. Defendants deny any remaining allegations contained in Paragraph 134 of Plaintiffs' Complaint.

135. Defendants deny the allegations contained in Paragraph 135 of Plaintiffs' Complaint.

136. Defendants deny the allegations contained in Paragraph 136 of Plaintiffs' Complaint.

137. Defendants deny the allegations contained in Paragraph 137 of Plaintiffs' Complaint.

138. Defendants deny the allegations contained in Paragraph 138 of Plaintiffs' Complaint.

FIFTH CAUSE OF ACTION

BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

139. Defendants incorporate by reference their responses to Paragraphs 1-138 of Plaintiffs' Complaint as if fully set forth herein.

140. Defendants admit that Bard owns a facility where vena cava filters are manufactured, including filters under the trademark Denali™ Filter System, and further admit

that BPV designs, sells, markets, and distributes inferior vena cava filters, including filters under the trademark Denali™ Filter System. Defendants deny that they made any warranties, express or otherwise, other than those expressly stated on the device, packaging, or instructions that accompanied the device. Defendants deny the remaining allegations contained in Paragraph 140 of Plaintiffs' Complaint.

141. Defendants deny the allegations contained in Paragraph 141 of Plaintiffs' Complaint.

142. Defendants deny the allegations contained in Paragraph 142 of Plaintiffs' Complaint.

143. Defendants deny the allegations contained in Paragraph 143 of Plaintiffs' Complaint.

144. Defendants deny the allegations contained in Paragraph 144 of Plaintiffs' Complaint, including all sub-parts thereof.

146. Defendants deny the allegations contained in Paragraph 145 of Plaintiffs' Complaint.¹

146. Defendants deny the allegations contained in Paragraph 146 of Plaintiffs' Complaint.

147. Defendants deny the allegations contained in Paragraph 147 of Plaintiffs' Complaint.

148. Defendants deny the allegations contained in Paragraph 148 of Plaintiffs' Complaint.

SIXTH CAUSE OF ACTION

NEGLIGENT MISREPRESENTATION

149. Defendants incorporate by reference their responses to Paragraphs 1-148 of Plaintiffs' Complaint as if fully set forth herein.

¹ Defendants note that, in their Complaint, Plaintiffs have misnumbered Paragraph 145, numbering it 146 instead. For the ease of the Court, Defendants have not changed the numbering of this Paragraph.

1 150. Defendants deny the allegations contained in Paragraph 150 of Plaintiffs'
2 Complaint, including all sub-parts thereof.

3 151. Defendants deny the allegations contained in Paragraph 151 of Plaintiffs'
4 Complaint.

5 152. Defendants deny the allegations contained in Paragraph 152 of Plaintiffs'
6 Complaint.

7 153. Defendants deny the allegations contained in Paragraph 153 of Plaintiffs'
8 Complaint.

9 154. Defendants deny the allegations contained in Paragraph 154 of Plaintiffs'
10 Complaint.

11 155. Defendants deny the allegations contained in Paragraph 155 of Plaintiffs'
12 Complaint.

13 156. Defendants deny the allegations contained in Paragraph 156 of Plaintiffs'
14 Complaint.

15 157. Defendants deny the allegations contained in Paragraph 157 of Plaintiffs'
16 Complaint.

17 158. Defendants deny the allegations contained in Paragraph 158 of Plaintiffs'
18 Complaint.

19 159. Defendants deny the allegations contained in Paragraph 159 of Plaintiffs'
20 Complaint.

21 **LOSS OF CONSORTIUM CLAIM**

22 160. Defendants incorporate by reference their responses to Paragraphs 1-159 of
23 Plaintiffs' Complaint as if fully set forth herein.

24 161. Defendants are without knowledge or information sufficient to admit or deny
25 the allegations contained in Paragraph 161 of Plaintiffs' Complaint and, on that basis, deny
26 them.

1 162. Defendants deny the allegations contained in Paragraph 162 of Plaintiffs'
2 Complaint.

3 **PUNITIVE DAMAGES ALLEGATIONS**

4 163. Defendants incorporate by reference their responses to Paragraphs 1-162 of
5 Plaintiffs' Complaint as if fully set forth herein.

6 164. Defendants deny the allegations contained in Paragraph 164 of Plaintiffs'
7 Complaint.

8 165. Defendants deny the allegations contained in Paragraph 165 of Plaintiffs'
9 Complaint, including all sub-parts thereof.

10 166. Defendants deny the allegations contained in Paragraph 166 of Plaintiffs'
11 Complaint.

12 167. Defendants deny the allegations contained in Paragraph 167 of Plaintiffs'
13 Complaint.

14 **PRAYER FOR RELIEF**

15 Furthermore, responding to the unnumbered Paragraph, including sub-parts, following
16 the heading "PRAYER FOR RELIEF" and beginning "WHEREFORE," Defendants deny the
17 allegations contained in such Paragraph and all sub-parts thereof.

18 Defendants further deny each and every allegation not specifically admitted herein.

19 Defendants allege as affirmative defenses the following:

20 1. Plaintiffs' Complaint filed herein fails to state a claim or claims upon which
21 relief can be granted under Rule 12 of the Federal Rules of Civil Procedure.

22 2. The sole proximate cause of Plaintiffs' damages, if any were sustained, was the
23 negligence of a person or persons or entity for whose acts or omissions Defendants were and
24 are in no way liable.

25 3. Plaintiffs' claims are barred, in whole or in part, by the applicable statutes of
26 limitations and/or statute of repose.

1 4. If Plaintiffs have been damaged, which Defendants deny, any recovery by
2 Plaintiffs are barred to the extent Plaintiffs voluntarily exposed themselves to a known risk
3 and/or failed to mitigate their alleged damages. To the extent Plaintiffs have failed to
4 mitigate their alleged damages, any recovery shall not include alleged damages that could
5 have been avoided by reasonable care and diligence.

6 5. If Plaintiffs have been damaged, which Defendants deny, such damages were
7 caused by the negligence or fault of Plaintiffs.

8 6. If Plaintiffs have been damaged, which Defendants deny, such damages were
9 caused by the negligence or fault of persons and/or entities for whose conduct Defendants are
10 not legally responsible.

11 7. The conduct of Defendants and the subject product at all times conformed with
12 the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301, *et seq.*, and other pertinent
13 federal statutes and regulations. Accordingly, Plaintiffs' claims are barred, in whole or in
14 part, under the doctrine of federal preemption, and granting the relief requested would
15 impermissibly infringe upon and conflict with federal laws, regulations, and policies in
16 violation of the Supremacy Clause of the United States Constitution.

17 8. If Plaintiffs have been damaged, which Defendants deny, such damages were
18 caused by unforeseeable, independent, intervening, and/or superseding events for which
19 Defendants are not legally responsible.

20 9. There was no defect in the product at issue with the result that Plaintiffs are not
21 entitled to recover against Defendants in this cause.

22 10. If there were any defect in the products – and Defendants deny that there were
23 any defects – nevertheless, there was no causal connection between any alleged defect and
24 the product on the one hand and any damage to Plaintiffs on the other with the result that
25 Plaintiffs are not entitled to recover against Defendants in this cause.

26 11. Plaintiffs' injuries, losses or damages, if any, were caused by or contributed to
27 by other persons or entities that are severally liable for all or part of Plaintiffs' alleged
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1 injuries, losses or damages. If Defendants are held liable to Plaintiffs, which liability is
2 specifically denied, Defendants are entitled to contribution, set-off, and/or indemnification,
3 either in whole or in part, from all persons or entities whose negligence or fault proximately
4 caused or contributed to cause Plaintiffs' alleged damages.

5 12. Plaintiffs' claims are barred to the extent that the injuries alleged in the
6 Complaint were caused by the abuse, misuse, abnormal use, or use of the product at issue in a
7 manner not intended by Defendants and over which Defendants had no control.

8 13. Plaintiffs' claims are barred to the extent that the injuries alleged in the
9 Complaint were caused by a substantial change in the product after leaving the possession,
10 custody, and control of Defendants.

11 14. Plaintiffs' breach of warranty claims are barred because: (1) Defendants did not
12 make any warranties, express or implied, to Plaintiffs; (2) there was a lack of privity between
13 Defendants and Plaintiffs; and (3) notice of an alleged breach was not given to the seller or
14 Defendants.

15 15. Plaintiffs' claims for breach of implied warranty must fail because the product
16 was not used for its ordinary purpose.

17 16. Defendants neither had nor breached any alleged duty to warn with respect to
18 the product, with the result that Plaintiffs are not entitled to recover in this cause.

19 17. Plaintiffs' claims are barred by Defendants' dissemination of legally adequate
20 warnings and instructions to learned intermediaries.

21 18. At all relevant times, herein, Plaintiffs' physicians were in the position of
22 sophisticated purchasers, fully knowledgeable and informed with respect to the risks and
23 benefits of the subject product.

24 19. If Plaintiffs' has been damaged, which Defendants deny, the actions of persons
25 or entities for whose conduct Defendants are not legally responsible and the independent
26 knowledge of these persons or entities of the risks inherent in the use of the product and other
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1 independent causes, constitute an intervening and superseding cause of Plaintiffs' alleged
2 damages.

3 20. To the extent that injuries and damages sustained by Plaintiffs, as alleged in
4 Plaintiffs' Complaint, were caused directly, solely, and proximately by sensitivities, medical
5 conditions, and idiosyncrasies peculiar to Plaintiffs not found in the general public, they were
6 unknown, unknowable, or not reasonably foreseeable to Defendants.

7 21. Defendants believe, and upon that ground allege, that Plaintiffs were advised of
8 the risks associated with the matters alleged in Plaintiffs' Complaint and knowingly and
9 voluntarily assumed them. Pursuant to the doctrine of assumption of the risk, informed
10 consent, release, waiver, or comparative fault, this conduct bars in whole or in part the
11 damages that Plaintiffs seek to recover herein.

12 22. At all relevant times during which the device at issue was designed, developed,
13 manufactured, and sold, the device was reasonably safe and reasonably fit for its intended
14 use, was not defective or unreasonably dangerous, and was accompanied by proper warnings,
15 information, and instructions, all pursuant to generally recognized prevailing industry
16 standards and state-of-the-art in existence at the time.

17 23. Plaintiffs' claims are barred because Plaintiffs suffered no injury or damages as
18 a result of the alleged conduct and do not have any right, standing, or competency to maintain
19 claims for damages or other relief.

20 24. Plaintiffs' claims are barred, in whole or in part, by the doctrines of waiver,
21 estoppel, and/or laches.

22 25. If Plaintiffs suffered any damages or injuries, which are denied, Defendants
23 state that Plaintiffs' recovery is barred, in whole or in part, or subject to reduction, under the
24 doctrines of contributory and/or comparative negligence.

25 26. In the further alternative, and only in the event that it is determined that
26 Plaintiffs are entitled to recover against Defendants, recovery should be reduced in proportion
27 to the degree or percentage of negligence, fault or exposure to products attributable to
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1 Plaintiffs, any other defendants, third-party defendants, or other persons, including any party
2 immune because bankruptcy renders them immune from further litigation, as well as any
3 party, co-defendant, or non-parties with whom Plaintiffs have settled or may settle in the
4 future.

5 27. Should Defendants be held liable to Plaintiffs, which liability is specifically
6 denied, Defendants would be entitled to a setoff for the total of all amounts paid to Plaintiffs
7 from all collateral sources.

8 28. Plaintiffs' claims may be barred, in whole or in part, from seeking recovery
9 against Defendants pursuant to the doctrines of res judicata, collateral estoppel, release of
10 claims, and the prohibition on double recovery for the same injury.

11 29. The injuries and damages allegedly sustained by Plaintiffs may be due to the
12 operation of nature or idiosyncratic reaction(s) and/or pre-existing condition(s) in Plaintiffs,
13 over which Defendants had no control.

14 30. The conduct of Defendants and all activities with respect to the subject product
15 have been and are under the supervision of the Federal Food and Drug Administration
16 ("FDA"). Accordingly, this action, including any claims for monetary and/or injunctive relief,
17 is barred by the doctrine of primary jurisdiction and exhaustion of administrative remedies.

18 31. Defendants assert any and all defenses, claims, credits, offsets, or remedies
19 provided by the Restatements (Second and Third) of Torts and reserve the right to amend
20 their Answer to file such further pleadings as are necessary to preserve and assert such
21 defenses, claims, credits, offsets, or remedies.

22 32. The device at issue complied with any applicable product safety statute or
23 administrative regulation, and therefore Plaintiffs' defective design and warnings-based
24 claims are barred under the Restatement (Third) of Torts: Products Liability § 4, *et seq.* and
25 comments thereto.

26 33. Plaintiffs cannot show that any reasonable alternative design would have
27 rendered the Denali™ Filter inferior vena cava filter device as alleged in Plaintiffs'
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1 Complaint to be safer overall under the Restatement (Third) of Product Liability § 2, cmt. f,
2 nor could Defendants have known of any alternative design that may be identified by
3 Plaintiffs.

4 34. The device at issue was not sold in a defective condition unreasonably
5 dangerous to the user or consumer, and therefore Plaintiffs' claims are barred under the
6 Restatement (Second) of Torts: Products Liability § 402A and comments thereto, and
7 comparable provisions of the Restatement (Third) of Torts (Products Liability).

8 35. At all relevant times during which the device at issue was designed, developed,
9 manufactured, and sold, the device was reasonably safe and reasonably fit for its intended
10 use, was not defective or unreasonably dangerous, and was accompanied by proper warnings,
11 information, and instructions, all pursuant to generally recognized prevailing industry
12 standards and state-of-the-art in existence at the time.

13 36. Defendants specifically plead all affirmative defenses under the Uniform
14 Commercial Code ("UCC") now existing or which may arise in the future, including those
15 defenses provided by UCC §§ 2-607 and 2-709.

16 37. Plaintiffs' alleged damages, if any, should be apportioned among all parties at
17 fault, and any non-parties at fault, pursuant to the Uniform Contribution Among Tortfeasors
18 Act.

19 38. No act or omission of Defendants was malicious, willful, wanton, reckless, or
20 grossly negligent, and, therefore, any award of punitive damages is barred.

21 39. To the extent the claims asserted in Plaintiffs' Complaint are based on a theory
22 providing for liability without proof of defect and proof of causation, the claims violate
23 Defendants' rights under the Constitution of the United States and analogous provisions of
24 the New Jersey Constitution.

25 40. Regarding Plaintiffs' demand for punitive damages, Defendants specifically
26 incorporate by reference any and all standards of limitations regarding the determination
27 and/or enforceability of punitive damages awards that arose in the decisions of *BMW of*
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1 *No. America v. Gore*, 517 U.S. 559 (1996); *Cooper Industries, Inc. v. Leatherman Tool*
 2 *Group, Inc.*, 532 U.S. 424 (2001); *State Farm Mut. Auto Ins. Co. v. Campbell*, 123 S. Ct.
 3 1513 (2003); and *Exxon Shipping Co. v. Baker*, No. 07-219, 2008 U.S. LEXIS 5263 (U.S.
 4 June 25, 2008) and their progeny as well as other similar cases under both federal and state
 5 law.

6 41. Plaintiffs' claims for punitive or exemplary damages violate, and are therefore
 7 barred by, the Fourth, Fifth, Sixth, Eighth and Fourteenth Amendments to the Constitution of
 8 the United States of America, and similar provisions of the New Jersey Constitution, on
 9 grounds including the following:

- 10 (a) it is a violation of the Due Process and Equal Protection Clauses of the
 11 Fourteenth Amendment of the United States Constitution to impose
 12 punitive damages, which are penal in nature, against a civil defendant
 13 upon the plaintiff satisfying a burden of proof which is less than the
 14 "beyond a reasonable doubt" burden of proof required in criminal cases;
- 15 (b) the procedures pursuant to which punitive damages are awarded may
 16 result in the award of joint and several judgments against multiple
 17 defendants for different alleged acts of wrongdoing, which infringes
 18 upon the Due Process and Equal Protection Clauses of the Fourteenth
 19 Amendment of the United States Constitution;
- 20 (c) the procedures to which punitive damages are awarded fail to provide a
 21 reasonable limit on the amount of the award against Defendants, which
 22 thereby violates the Due Process Clause of the Fourteenth Amendment
 23 of the United States Constitution;
- 24 (d) the procedures pursuant to which punitive damages are awarded fail to
 25 provide specific standards for the amount of the award of punitive
 26 damages which thereby violates the Due Process Clause of the
 27 Fourteenth Amendment of the United States Constitution;

- 1 (e) the procedures pursuant to which punitive damages are awarded result in
2 the imposition of different penalties for the same or similar acts, and thus
3 violate the Equal Protection Clause of the Fourteenth Amendment of the
4 United States Constitution;
- 5 (f) the procedures pursuant to which punitive damages are awarded permit
6 the imposition of punitive damages in excess of the maximum criminal
7 fine for the same or similar conduct, which thereby infringes upon the
8 Due Process Clause of the Fifth and Fourteenth Amendments and the
9 Equal Protection Clause of the Fourteenth Amendment of the United
10 States Constitution;
- 11 (g) the procedures pursuant to which punitive damages are awarded permit
12 the imposition of excessive fines in violation of the Eighth Amendment
13 of the United States Constitution;
- 14 (h) the award of punitive damages to the plaintiffs in this action would
15 constitute a deprivation of property without due process of law; and
- 16 (i) the procedures pursuant to which punitive damages are awarded permit
17 the imposition of an excessive fine and penalty.

18 42. Defendants expressly reserve the right to raise as an affirmative defense that
19 Plaintiffs have failed to join all parties necessary for a just adjudication of this action, should
20 discovery reveal the existence of facts to support such defense.

21 43. The design complained of in Plaintiffs' Complaint, the alleged defects of the
22 product, and/or any alternative design claimed by Plaintiffs were not known and, in light of
23 the existing, reasonably-available scientific and technological knowledge, could not have
24 been known at the time the product at issue was designed, manufactured, and sold. Any
25 alleged alternative design was not scientifically or technologically feasible or economically
26 practical.

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**Attorney for Defendants C. R. Bard, Inc. and
Bard Peripheral Vascular, Inc.**

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on March 10, 2016, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system which will send notification of such filing to all counsel of record.

s/Richard B. North, Jr.
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